



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127 JEN

January 3, 2002

VIA FEDERAL EXPRESS

Thomas C. Elliott, President
Farmsoy Company
96C The Farm
Summertown, TN 38483

Warning Letter No. 02-NSV-08

Dear Mr. Elliott:

On July 16, 2001 the Food and Drug Administration conducted an inspection of your facility located at 96C The Farm, Summertown, TN. During the inspection, our investigator collected a "Farmsoy Tofu" label for review. Our review revealed that "Farmsoy Tofu" is misbranded within the meaning of Section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Part 101, Food Labeling. You can find this Act and 21 CFR Part 101 through links in FDA's homepage at www.fda.gov.

Your firm has submitted a small business exemption from nutritional labeling to FDA. However, foods lose their exemption status if the label provides nutritional information. [21 CFR 101.9(j)(18)] Furthermore, your firm was notified in a letter from FDA, dated October 17, 1997 that the small business exemption was valid only if the label did not provide any nutritional information.

Our review of the label revealed the following:

- Nutritional information is not listed in accordance with **21 CFR 101.9(c)**. For example:
 - five of the required nutrients are missing, i.e., saturated fat, sugars, cholesterol, and vitamins A and C
 - acceptable nutrient titles are not used, i.e., "fat" is used instead of "total fat" or "fat, total" and "carbohydrates" is used instead of "total carbohydrate" or "carbohydrate, total"
 - declared nutrients are not in the required order
 - nutrient values are not listed as a percentage of daily value
 - number of calories from fat is not listed
 - nutrient values are not listed in the proper increments
- The nutritional information is not formatted in accordance with **21 CFR 101.9(d)**
- Serving size declaration was not determined in accordance with **21 CFR 101.9(b)(1), (2), and (5)**.
- Servings per container is not listed. [21 CFR 101.9(b)(8)]

- Serving size is not followed by the equivalent metric quantity in parenthesis. [21 CFR 101.9(b)(7)]

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

The following document is enclosed to assist you with compliance:

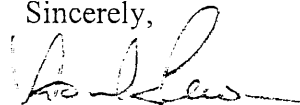
- Food Labeling Guide

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of the steps that you have taken to bring your farm into compliance with the law. Your response should include each step taken to correct the violations and prevent their recurrence. If you cannot complete all corrections within 15 working days, we expect you to explain the reason for your delay and state when any remaining deviations will be corrected. Please include copies of any documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Karen Gale Sego, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,



Howard E. Lewis

Acting Director, New Orleans District

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Enclosure:

Food Labeling Guide

cc:

Jimmie D. Hopper, Director
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Tennessee Dept. of Agriculture
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Melrose Station, PO Box 40627
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